

Genetic Privacy and Genetic Discrimination Matrix for Washington State
DRAFT for June 25th, 2002 Meeting

Note: The Meeting Summaries prepared after each GTF meeting may be helpful cross-references for many topics. The January 3, 2002 Meeting Summary contains additional information about HIPAA, RCW 70.02, SB 6199, EO 00-03, 45 CFR 46 and the ADA. The February 25, 2002 Meeting Summary contains additional information about the OIC Rules, RCW 49.60/WAC 162, HIPAA, use of genetic information in employment, genetic testing of minors, and genetic information and adoption. The April 12, 2002 Meeting Summary contains additional information on 45 CFR 46 and FDA regulations 21 CFR 50 and 21CFR 56.

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02^	Patient’s Bill of Rights SB 6199	Governor’s Executive Order on Privacy EO 00-03	45 CFR 46 ^ψ 21 CFR 50 21 CFR 56	American’s with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Encompasses/Defines Genetic Information	<u>Yes</u> , ‘health information’ is defined broadly and is generally interpreted to encompass genetic information. <u>No</u> . Does not specifically define <i>genetic information</i> separate from health information.	<u>Yes</u> , the ‘health care information’ includes an individual’s deoxyribonucleic acid and identified sequence of chemical base pairs. <u>No</u> . Does not specifically define <i>genetic information</i> separate from health care information.	<u>Yes</u> , it uses the same definition of ‘health care information’ as RCW 70.02. <u>No</u> . Does not specifically define <i>genetic information</i> separate from health care information.	<u>Yes</u> , it protects all readily identifiable personal information. <u>No</u> . Does not specifically define <i>genetic information</i> separately from other types of personal information.	<u>Yes</u> , 45 CFR 46 applies to all personally identifiable information used for research purposes. 21 CFR 50/56 apply to all research regulated by the FDA. <u>No</u> . Do not specifically define <i>genetic information</i> .	<u>Yes</u> , the EEOC interprets the ADA “regarded as” clause to encompass existing and pre-symptomatic genetic disorders. <u>No</u> . Does not specifically define <i>genetic information</i> .	<u>Yes</u> , WAC 284-43-720 genetic information is not a pre-existing condition without a diagnosis of the condition. <u>No</u> . Does not specifically define <i>genetic information</i> .	<u>Yes</u> , disability is broadly defined and is interpreted to encompass genetic disorders. WAC 162.22.020 <u>No</u> . Does not specifically define <i>genetic information</i> separate from disability.
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Requires Authorization for the Release of Genetic Information to Third Parties Within the Health Care System	<u>Yes</u> , requires patients’ consent/authorization for the release of any health information. Blanket consent is acceptable for the release of health information for treatment, health care operations, and payment. Specific authorization is required for all other releases. Exceptions exist for public health, research, law enforcement, and other uses required by law.	<u>Yes</u> , 70.02.020 A health care provider is required to obtain written authorization from an individual for the release of health care information to any other person. (EXCEPT as outlined in 70.02.050)	<u>Yes</u> , Patient consent is required for the disclosure of health care information.	<u>Yes</u> , it prevents state agencies, employees and contractors from selling or disclosing personal identifying information.	<u>Yes</u> , 45 CFR 46 requires authorization to release identifiable information, except as required by law. To obtain additional protections against compelled disclosure, researchers may apply for a federal certificate of confidentiality. 21 CFR 50 requires notification of the extent to which confidentiality of information will be protected and a notification that the FDA may inspect research records.	<u>N/A</u> .	<u>Yes</u> , requires insurers to protect patients’ privacy according to existing state and federal laws.	<u>N/A</u> .

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Requires Authorization to Release Genetic Information to Entities Outside of the Health Care System (banks, schools, loan agencies, etc)	<u>Yes</u> , requires specific authorization for disclosure but it does not protect the information once it leaves the health care system. (some exceptions)	<u>Yes</u> , requires specific authorization for disclosure but it does not protect the information once it leaves the health care system. (some exceptions)	<u>Yes</u> , it requires specific authorization for disclosure of health care information.	<u>Yes</u> , it prohibits state agencies, employees or contractors from disclosing personal information to any party without legal authority.	<u>Yes</u> , 45 CFR 46 requires authorization to release identifiable information to all entities except when required by law. 21 CFR 50 requires notification of the extent to which confidentiality of information will be protected and a notification that the FDA may inspect research records.	N/A	<u>Yes</u> , requires insurers to protect patients’ privacy according to existing state and federal laws.	N/A
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Includes Specific Informed Consent Requirements for the Disclosure or Use of Genetic Information	<u>Yes</u> . Patients must provide specific consent for the release of health information for treatment, payment and administrative purposes. Patients must authorize all other disclosures.	<u>Yes</u> . It requires specific authorization for disclosure. <u>No</u> . It does not require specific authorization for use.	<u>Yes</u> . It mandates the same consent requirements as 70.02	<u>N/A</u> .	<u>Yes</u> . 45 CFR 46 Requires consent for disclosure of any identifiable information, but does not specify genetic information. 21 CFR 50 requires informed consent for participating in research including notification of the extent to which confidentiality of information will be protected and a notification that the FDA may inspect research records.	N/A	<u>No</u> .	<u>N/A</u> .

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Protects Human Biological Material (tissue, cells or serum) from Unauthorized Release or Use	<u>No</u> , defines health information as oral, written or electronic; does not imply or specify biological material.	<u>No</u> , does not explicitly refer to biological material.	<u>N/A</u> .	<u>N/A</u> .	<u>Yes</u> , 45 CFR 46 considers human biological samples from living humans stored with links to identifiers as research involving human subjects. 21 CFR 50 requires an explanation of the procedures to be followed including use of biological materials.	<u>N/A</u> .	<u>N/A</u> .	<u>N/A</u>
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Regulates Access to Genetic Information by Blood or Legal Relatives	<u>Yes</u> . Release of health information is permitted with the individual's consent (if the individual is present) and/or if the covered entity reasonably infers consent based on medical judgment or lack of objection. Health care providers must notify Patients that they have the right to agree or object to disclosure practices such as disclosure to family. (164.510)	<u>Yes</u> . 70.02.050 1(e) Health care providers may orally relate an individual's health care information to family members and others with a close personal relationship to the individual without the individual's consent unless the individual has instructed the health care provider in writing not to disclose the information. RCW 70.02.130 A person authorized to consent to health care for another may also exercise the right to access and authorize disclosure of the information.	<u>Maybe</u> . Health carriers and insurers are required to adopt policies and procedures that conform administrative, business, and operational practices to protect an enrollee's right to privacy or right to confidential health care services granted under state or federal laws. (SB 6199 Section 5). State and federal laws allow relatives to have access to health care information.	<u>Maybe</u> . State agencies are required to "provide reasonable assurances that those [records] containing confidential personal information are properly safeguarded". This may protect information from release to related third parties, but it may not. <u>No</u> . No specific mention is made about release of or access to information to family members or related third parties.	<u>Yes</u> , 46.116 (a) (5) and 21 CFR 50 require that informed consent include an explanation of the extent to which confidentiality of identifiable records will be maintained. This is interpreted to include information about to whom information may be given and under what circumstances. <u>No</u> . There are no specific limits or guidelines regarding the release of information.	N/A	N/A	N/A

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Regulates the <u>Use</u> of Genetic Information by Health Insurance Companies for Determining Eligibility or Setting Rates	<u>Yes</u> , the portability component states that genetic information may not be considered a pre-existing condition unless a patient has a diagnosis. It also provides that insurers cannot use genetic information to apply different eligibility requirements or rates to individuals within a group plan. <u>No</u> , it does not regulate what information an insurance company may ask for.	<u>No</u> , it does not generally apply to insurers. (70.02.045 does prohibit third party payers from releasing health care information)	<u>Yes</u> , it makes insurers subject to the provisions of the UHCIA in regards to disclosure and protection of health care information, although exemptions are broader with respect to insurers activity. <u>No</u> , it does not regulate how the insurer can use the information in practice.	<u>No</u> , only applies to state governments agencies, employees and contractors.	<u>N/A.</u>	<u>N/A.</u>	<u>Yes</u> , insofar as defining a pre-existing condition is concerned and insofar as the rules disallow “high-risk” rate setting based on health status by health plans. (WAC 284-43-720) (RCW 48.44.23). See RCW 48.43.005 for list of exceptions to ‘health plan’	<u>Yes</u> , addresses issues related to discrimination based on status in a protected class (e.g. disabled)
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Regulates the <u>Use</u> of Genetic Information by Life Insurance Companies for Determining Eligibility or Setting Rates	<u>No</u> , it only applies to health insurance.	<u>No</u> , it only applies to health insurance.	<u>No</u> , it only applies to health insurance.	<u>No</u> , only applies to state governments agencies, employees and contractors.	<u>N/A.</u>	<u>N/A.</u>	<u>Yes</u> , May allow use of genetic information to deny a life insurance policy but prohibits the cancellation of a policy based on new information obtained after the policy was issued. Allows the use of genetic information to set rates but not change them. WAC 284.84.100	<u>Yes</u> , addresses issues related to discrimination based on status in a protected class (e.g. disabled)

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Regulates <u>Use</u> of Genetic Information by Other Entities (e.g. banking, housing, schools) for Determining Eligibility or Setting Rates	<u>No</u> , does not apply to genetic information outside of the health care system.	<u>No</u> .	<u>No</u> , it only applies to health insurance.	<u>No</u> , only applies to state governments agencies, employees and contractors.	<u>N/A</u> .	<u>N/A</u>	<u>N/A</u>	<u>Yes</u> , addresses issues related to discrimination based on status in a protected class (e.g. if someone with a genetic predisposition was perceived as or treated as disabled, they would be protected)
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Regulates <u>Use</u> of Genetic Information by Employers for Determining Employment Status or Health Insurance Benefits Eligibility	<u>Yes</u> , insofar as an employer cannot deny an employee health care benefits offered to other employees based on genetic information. <u>No</u> , it does not regulate use of genetic information for employment decisions.	<u>N/A</u> .	<u>N/A</u> .	<u>Maybe</u> , it regulates the collection and release of readily identifiable information if the employer is a state agency or contractor. <u>No</u> , it does not regulate use of genetic information for employment decisions.	<u>N/A</u> .	<u>Yes</u> , requires employers to make reasonable accommodations for person with disabilities and disallows them from requiring medical/genetic testing that is not job-related or consistent with business necessity.	<u>No</u> .	<u>Yes</u> , addresses issues related to discrimination based on status in a protected class (e.g. if someone with a genetic predisposition was perceived as or treated as disabled, they would be protected)

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Protects Asymptomatic People with a Genetic Susceptibility from Unauthorized Disclosure of Genetic Information and/or Discrimination Based on Genetic Status	<u>Yes</u> , individuals with a record of a genetic susceptibility are protected from the disclosure of that information. <u>Yes</u> , from health insurance discrimination as described above. <u>No</u> , it does not protect from employment or other discrimination.	<u>Yes</u> , individuals with a record of a genetic susceptibility are protected from the disclosure of that information if it is part of their health care/medical record. <u>No</u> , it does not protect against employment or other discrimination.	<u>No</u> , it does not regulate health insurance eligibility requirements, however it mandates that those requirements be disclosed prior to enrollment. (pre-existing conditions are defined and regulated elsewhere)	<u>Maybe</u> , it limits “the collection of personal information to that reasonably necessary for purposes of program implementation, authentication of identity, security, and other legally appropriate agency operations.” <u>No</u> , it does not protect against employment or other discrimination.	<u>Yes</u> , 46.116 (a) (5) and 21 CFR 50 requires that informed consent include an explanation of the extent to which confidentiality of identifiable records will be maintained. This is interpreted to include information about to whom information may be given and under what circumstances. <u>No</u> . There are no specific limits or guidelines regarding the release of information.	<u>Yes</u> , the EEOC interprets the “regarded as” clause to be protective of persons with pre-symptomatic genetic conditions.	<u>Yes</u> , by limiting the use of genetic information without a diagnosis in the determination of a pre-existing condition. (WAC 284-43-720)	<u>Yes</u> , definition of disability includes conditions that are perceived to exist whether or not they exist in fact.
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Protects Symptomatic People with a Genetic Disorder from Unauthorized Disclosure of Genetic Information and/or Discrimination Based on Genetic Status	<u>Yes</u> , individuals with a record of a genetic susceptibility are protected from the disclosure of that information. <u>No</u> , it does not protect against employment or other discrimination. <u>Yes</u> , it protects from health insurance discrimination as described above.	<u>Yes</u> , individuals with a record of a genetic susceptibility are protected from the disclosure of that information if it is part of their health care/medical record. <u>No</u> , it does not protect against employment or other discrimination.	<u>No</u> , it does not regulate health insurance eligibility requirements, however it mandates that those requirements are disclosed prior to enrollment. (pre-existing conditions are defined and regulated elsewhere)	<u>Maybe</u> , it limits “the collection of personal information to that reasonably necessary for purposes of program implementation, authentication of identity, security, and other legally appropriate agency operations. <u>No</u> , it does not protect against employment or other discrimination.	<u>Yes</u> , 46.116 (a) (5) and 21 CFR 50 requires that informed consent include an explanation of the extent to which confidentiality of identifiable records will be maintained including information about to whom information may be given and under what circumstances. <u>No</u> . There are no specific limits or guidelines regarding the release of information. <u>N/A</u> to discrimination issues.	<u>Yes</u> , an individual with a disability under the ADA is “a person who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment.”	<u>Yes</u> , to the extent that the disease is not classifiable as a pre-existing condition. (WAC 284-43-720)	<u>Yes</u> , definition of disability includes conditions that are perceived to exist whether or not they exist in fact.

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Regulates the Genetic Testing of Minor Children	N/A	<u>Other</u> RCW13.64.060 gives emancipated minors the right to give informed consent for health care services.	N/A	N/A	<u>Yes.</u> 45 CFR46 and title 21 contain special provisions for research involving children. <u>No.</u> Does not speak directly to genetic testing.	N/A	<u>Other:</u> The Regence Group laboratory policy (9/15/99) regarding genetic testing: genetic testing in children to confirm symptoms or predict adult onset diseases is not medically necessary unless direct medical benefit is contingent upon the test result.	N/A
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Regulates Use and or Disclosure of Genetic Information under Circumstances Related to Adoption	<u>No.</u> There are no restrictions placed on the use of health information in adoption. The only reference made to adoption limits an insurers ability to impose pre-existing condition exclusions on adopted children.	<u>No.</u> There are no provisions in this law regarding the use of genetic information in the adoption processes. <u>Other:</u> RCW 26.33.350 mandates that all persons, firms, societies, associations, corporations and state agencies involved in an adoption disclose all known and available medical information to the adoptive parents.	N/A	<u>Maybe.</u> Requires state agencies to provide reasonable assurances that confidential personal information is properly safeguarded. State agencies dealing with adoptions fall under the purview of this EO. <u>No.</u> There is no mention of the adoption process.	N/A	N/A	N/A (?)	N/A (?)

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Regulates Release of and Access to Genetic Information Held by Entities Outside of the Health Care System	<u>No.</u> Does not address the protection of health information pursuant to its release to uncovered entities (health oversight agencies, courts, law enforcement, etc). <u>Maybe.</u> There are limited protections provided against unauthorized disclosure of health information in the context of the legal system. Specifically, Sec. 3486 part (e)	<u>No.</u> Does not pertain to the use of health care information once it has been disclosed by a health care provider to a third party outside the health care system (law enforcement, courts, public health agencies, etc). <u>Yes.</u> The parameters for the release of information in research are clearly outlined in this law.	<u>No.</u> Has the same limitations as RCW 70.02	<u>Yes,</u> a state agency, before contracting with an outside entity, must ascertain that the contractor has protections in place and will not allow or make unauthorized disclosures of the information. However, it does not provide specific protections that follow the information upon its release to any other entity.	<u>Yes.</u> 46.116 (a) (5) requires all agencies receiving federal funds or regulated by a federal agency for research to use informed consent procedures that include an explanation of the extent to which confidentiality of identifiable records will be maintained. <u>No.</u> There are no specific limits or guidelines regarding the release of information.			
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Includes Exceptions for Research	<u>Yes.</u> 164.512 (i) allows disclosure of health information for research with appropriate waiver and IRB or other oversight board approval. 164.502 (d) provides guidelines for de-identifying protected health information	<u>Yes.</u> 70.02.050 1(g) allows disclosure of health care information for research without consent if approved by an IRB. Parameters for disclosure of health care information without consent for use in research are outlined.	<u>N/A</u>	<u>N/A</u>	<u>Yes,</u> some research may be exempt from IRB review. For example, privately funded research that is not regulated by a federal agency is not required by federal law to follow federal rules and guidelines. Also, some federally funded research may be exempt if it meets specific criteria. (See the April 12 meeting summary for more detail)	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>

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Regulatory Oversight and/or Enforcement and Penalties for Violations	<u>Yes.</u> The Health and Human Services Office for Civil Rights (OCR) enforces the HIPAA privacy rules. OCR relies on reports and formal complaints regarding violations. OCR will investigate claims of violations and seeks 'informal' resolutions of noncompliance. If an informal resolution cannot be met, OCR may apply civil monetary fines or work with the Justice Department to seek criminal prosecution. Civil monetary penalties are \$100 per violation and capped at \$25,000 per year. Criminal fines range from \$50,000 - \$250,000 and prison terms range from 1 to 10 years.	<u>Yes.</u> Provides for civil remedies for non-compliance to RCW 70.02. There is no oversight/regulatory body; claims of violations must be tried in court. The court may order actual damages but not incidental or consequential damages. <u>Other:</u> RCW 42.48.050 unauthorized disclosure of personally identifiable information by a researcher who obtained the information from a state agency is a gross misdemeanor subject to fines up to \$10,000 for each violation.	<u>Yes.</u> Permits individuals to sue violators; an independent review process may be requested.	<u>Yes.</u> Each state agency appoints a designee to receive and process citizen complaints regarding privacy violations. A representative from the governor's office oversees this EO and handles complaints not addressed to specific agencies.	<u>Yes.</u> Institutional Review Boards monitor compliance with federal and local regulations. IRBs rely on internal and external review and inspection of research proposals and reporting of violations by research subjects or others. Penalties include fines, suspension of research activities and suspension of federal funding for research involving humans. The FDA inspects entities regulated by the FDA for compliance with FDA regulations.	<u>Yes.</u> The Equal Employment Opportunities Commission is the regulatory body for the ADA. The EEOC relies on employees or others to report violations. The EEOC investigates reported violations and may sue violators in court.	<u>Yes.</u> The OIC receives and investigates reports of violations and can levy fines on violators.	<u>Yes.</u> The WA State Human Rights Commission is the regulatory body for RCW 49.60. The WSHRC receives and investigates complaints. The WSHRC may hold hearings and subpoena witnesses. If WSHRC efforts fail to remedy the problem, the matter may be sent to the Attorney General for litigation before the Administrative Law Judge.

*See March 2002 HHS Press Release and Fact Sheet regarding proposed changes to HIPAA privacy rules.

^ ESSB 5207 passed the state legislature in March 2002 and changed the definition of 'health care information' in RCW 70.02. The new definition is "Health care information" means any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care *including a patient's deoxyribonucleic acid and identified sequence of chemical base pairs*. The term includes any record of disclosures of health care information."

^ψ45 CFR 46 – "Protection of Human Subjects; 21 CFR 50 – "Informed Consent; 21 CFR 56 – "Institutional Review Boards" the text of these regulations can be found at http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html; http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr50_00.html; and http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr56_00.html respectively.

Other resources: Health Information Administration "HIPAA Policy Guide Matrix" at <http://depts.washington.edu/hia> under the "more information" section.